**IMPORTANT: DO NOT CHANGE THE FORMAT OF THE FORM. ANY CHANGE OR MODIFICATION OF THE FORM WILL RESULT IN REJECTION OF THE APPLICATION BY THE CANDIDATE.**

**For Reporting Adverse Consequences to Humans Participating in Research**

**All forms must be typewritten, signed, and submitted via email to** [**cu.ierb@chitkara.edu.in**](mailto:cu.ierb@chitkara.edu.in)

**IERB Approval Number:**

Study Title:

**Responsible Project Investigator:**

**Study Sponsor, if applicable:**

**Date of incident:**

**Date Reported:**

**Subject #:**

1. Date of PI/Supervisor’s knowledge of event [if different from the date above]:
2. Provide a description of the event:

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| --- |
|  |

Determination:

|  |  |
| --- | --- |
| Yes  No | **Unexpected** – in terms of nature, severity, or frequency: given (a) the research procedures are described in the protocol and related documents, e.g., protocol, consent form; and (b) the characteristics of the subject populations being studied  **Comment:** |
| Yes  No | Related or possible related to participation in the research – possibly related means there is a reasonable possibility that the incident may have been caused by the procedures involved in the research  **Comment:** |
| Yes  No | Placed subjects or others at a **greater risk of harm than was previously known or recognized** – includes physical, psychological, economic, or social harm  **Comment:** |

1. Proposed changes to protocol and/or study design:

|  |
| --- |
|  |

1. Proposed changes to informed consent or other supplemental material:

|  |
| --- |
|  |

1. If the event could have been prevented provide a proposed plan of what changes will be made so there are no related, future incidents:

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|  |

Determination: Unanticipated problems must meet all three criteria above. They must be (i) unexpected, (ii) related or possibly related to the research and (iii) suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized.

This incident       does or       does not constitute an unanticipated problem per OHRP guidance on reviewing and reporting problems

**INVESTIGATOR ASSURANCES**

I certify that the information supplied on this form is complete and correct.

Responsible Principal Investigator/Supervisor Date

**PLEASE NOTE: No form will be accepted without the signature of the Supervisor in case of PhD/Master/Bachelor students.**

**Any faculty who is an independent researcher must sign the form as the PI.**